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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,735	IDDAN ET AL.	
	Examiner	Art Unit	
	RENE TOWA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14,15,18,24-29,32,33,36,38-40,43 and 45-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12, 14-15, 18, 24-29, 32-33, 36, 38-40, 43 and 45-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 22, 2010 has been entered.

2. This Office action is responsive to an amendment filed January 21, 2010. Claims 1-12, 14-15, 18, 24-29, 32-33, 36, 38-40, 43 and 45-48 are pending. Claims 1-2, 10-11, 15, 18, 26, 32, 43 & 47-48 have been amended. Claims 13, 16-17, 19-23, 30-31, 34-35, 37, 41-42, 44 and 49-50 have been cancelled.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. **Claims 1, 3-4, 7, 10, 14, 24-25, 27, 29, 32, 36, 40, 43, 45, 47-48** are rejected under 35 U.S.C. 103(a) as being unpatentable over Meron et al. (US 2002/0109774) in view of Dunne et al. (US 6,626,834).

Meron et al. disclose an in-vivo sensing system (10, 50, 70) comprising a capsule-shaped transparent housing (see figs. 1B, 5 & 7); wherein the housing includes at least one imaging device (14, 54, 74) (see par 0039-0040, 0053-0055 & 0057-0058) configured to image any direction with respect to said housing (see figs. 5 & 7); wherein

the system includes at least one transmitter 16 (see par 0035); Meron et al. also disclose a method for imaging an in vivo site comprising the steps of:

inserting an in-vivo imaging device (54, 74) (see par 0016);

capturing images from any orientations with respect said housing (see par 0017);

wherein the method further comprises the step of transmitting data from the in-vivo imaging device (see par 0017); and,

wherein the method further includes reviewing the transmitted data (see par 0009 & 0017).

Meron et al. disclose a system and method, as described above, that fails to explicitly teach an in vivo sensing system as described in the claims.

In regards to **claim 1**, **Dunne et al.** disclose an in vivo sensing system comprising:

(a) a housing (12, 52) (see figs. 1-12) comprising:

(i) at least one imaging device 24 (see col. 12, lines 37-47);

(ii) at least one directional activator 26 within said imaging device 24 (see col. 9, lines 50-52; col. 10, lines 3-6);

(iii) at least one friction reducing (i.e. lubricant) mechanism 20 disposed between said housing (12, 52) said imaging device 24 (see col. 9, lines 41-49); and,

(b) at least one directional actuator (120, 146) external to said housing (12, 52) to control said at least one directional activator 26 so as to change the orientation of

said imaging device 24 with respect to said housing (12, 52) (see fig. 14; col. 12, lines 10-20; col. 15, lines 60-67; col. 16, lines 1-7).

In regards to **claim 3**, Dunne et al. disclose a system wherein the housing (12, 52) has a capsule shape (see figs. 1, 3 & 5; col. 13, lines 19-22).

In regards to **claim 4**, Dunne et al. disclose a system wherein the housing (12, 52) is collapsible (see fig. 7; col. 13, lines 60-65; col. 14, lines 6-11).

In regards to **claim 7**, Dunne et al. disclose a system wherein the housing (12, 52) is at least partially transparent (i.e. via acoustic window 14) (see figs. 1-4; col. 12, lines 58-63).

In regards to **claim 10**, Dunne et al. disclose a system wherein the imaging device 24 has a capsule shape (see fig. 1; col. 10, lines 3-6).

In regards to **claim 14**, Dunne et al. disclose a system wherein the directional activator 26 comprises at least one magnet (see fig. 1; col. 9, lines 50-52; col. 10, lines 3-6), and wherein the directional actuator (120, 146) comprises a magnetic field generator (i.e. current waveform generator 144, DC electricity) (see col. 12, lines 10-24; col. 15, lines 60-67; col. 16, lines 1-7).

In regards to **claim 24**, Dunne et al. disclose a system wherein the friction-reducing mechanism includes a liquid (i.e. oil) (see col. 9, lines 45-48).

In regards to **claim 25**, Dunne et al. disclose a system wherein the liquid is oil (i.e. Dow Corning Corp. number 704 diffusion pump oil) (see col. 9, lines 45-48).

In regards to **claim 27**, Dunne et al. disclose a system wherein the liquid is capable of being introduced into the housing (12, 52) in vivo (see col. 13, lines 6-10).

In regards to **claim 29**, Dunne et al. disclose a system wherein the liquid is at least partially transparent (see col. 15, lines 6-17).

In regards to **claim 32**, Dunne et al. disclose in vivo imaging system comprising:

(a) an outer covering (12, 52), said outer covering (12, 52) (see figs. 1-12) comprising:

(i) an image sensor 24 (see col. 12, lines 37-47), said image sensor 24 comprising at least one directional activator 26 (see col. 9, lines 50-52; col. 10, lines 3-6); and

(ii) a liquid 20 disposed between the outer covering (12, 52) and the sensor 24 (see col. 9, lines 41-49); and

(b) at least one directional actuator (120, 146) external to said outer covering (12, 52) configured to control said at least one directional activator 26 from outside said outer covering (12, 52) so as to change orientation of said image sensor 24 with respect to said outer covering (12, 52) (see fig. 14; col. 12, lines 10-20; col. 15, lines 60-67; col. 16, lines 1-7).

In regards to **claim 36**, Dunne et al. disclose a system wherein the at least one directional activator 26 comprises a magnet (see fig. 1; col. 9, lines 50-52; col. 10, lines 3-6), and wherein the at least one directional actuator (120, 146) comprises a magnetic field generator (i.e. current waveform generator 144, DC electricity) (see col. 12, lines 10-24; col. 15, lines 60-67; col. 16, lines 1-7).

In regards to **claim 43**, Dunne et al. disclose a method for imaging an in vivo site comprising the steps of:

providing an in-vivo imaging device 24 comprising a magnet 26, being disposed within a housing (12, 52) (see col. 9, lines 50-52; col. 10, lines 3-6) and being surrounded by a friction reducing material 20 within said housing (12, 52) (see col. 9, lines 41-49);

changing orientation of said in vivo imaging device 24 to a multitude of orientations with respect to said housing (12, 52) in a friction-reduced manner by application of an external force to said in-vivo imaging device 24 (see col. 10, lines 54-65); and,

capturing images from any of said multitude of orientations (see col. 11, lines 46-52).

In regards to **claim 45**, Dunne et al. disclose a method wherein the external force is electromagnetic force torque generating fields or magnetic torque generating fields (see col. 10, lines 54-65).

In regards to **claims 1, 3-4, 7, 10, 14, 24-25, 27, 29, 32, 36, 40, 45 & 47,** Meron et al. teach a system for wide angle imaging of body lumens by combining a plurality of images so as to most effectively view and image said body lumens (see abstract & par 0003); since Dunne et al. teach that it is known to volumetrically scan a target, which is located within a swept conical volume (see col. 11, lines 46-52), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system and method of Meron et al. with a housing having at least one

imaging device, at least one directional activator within said imaging device, at least one friction reducing mechanism between said housing and said imaging device, and at least one directional actuator as taught by Dunne et al. in order to achieve wide angle imaging of body lumens by combining a plurality of images so as to most effectively view and image said body lumens via volumetric scanning.

In regards to **claim 48**, similarly since Meron et al. teach a system for wide angle imaging of body lumens so as to most effectively view and image said body lumens (see abstract & par 0003); wherein the transmitted image is analyzed (reviewed) in real time (see par 0009); and Dunne et al. teach a method step of applying an external force to change the direction of the imaging device (see col. 10, lines 54-65), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system and method of Meron et al. as modified by Dunne et al. with a step of applying an external force to change the direction of the imaging device as taught by Dunne et al. based on the reviewed transmitted data as taught by Meron et al. in order to serially analyze the captured images.

5. **Claims 2, 6, 8-9, 18, 33 & 38-39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Meron et al. ('774) in view of Dunne et al. ('834) and further in view of Kilcoyne et al. (US 6,285,897).

Meron et al. as modified by Dunne et al. disclose an in-vivo system, as described above, that fails to explicitly teach an attachment mechanism or a pH sensor.

However, **Kilcoyne et al.** disclose an in-vivo system (see col. 3, lines 6-10) comprising:

(a) a housing 120:

wherein the housing 120 is an inert hydrocarbon (i.e. polyethylene) (see col. 6, lines 55-62);

(b) an attachment mechanism (see fig. 6) comprising anchors or fasteners such as tacks, pins, hooks, barbs, sutures, clips, staples (see col. 9, lines 5-51) or glue such as an adhesive (see col. 8, lines 48-60); and,

(c) at least one sensor (i.e. pH, temperature or pressure sensor) (see col. 5, lines 15-46).

In regards to **claims 2 & 6**, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Meron et al. as modified by Dunne et al. with a housing that includes a hydrocarbon as taught by Kilcoyne et al. in order to achieve a housing that is inert or biocompatible in the human body.

In regards to **claims 8-9 & 33**, Since Kilcoyne et al. teach other means for effectively anchoring an in-vivo system in the gastrointestinal track of a patient (see fig. 6), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Meron et al. as modified by Dunne et al. with an attachment mechanism as taught by Kilcoyne et al. in order to temporarily attach, anchor or stabilize the in-vivo device to the body lumen so as to collect physiological data therefrom.

In regards to **claims 18 & 38-39**, similarly, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system

of Meron et al. as modified by Dunne et al. with a pH sensor as taught by Kilcoyne et al. in order to achieve long-term monitoring of gastroesophageal reflux (GERD).

6. **Claims 11-12 & 26, 28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Meron et al. ('774) in view of Dunne et al. ('834) and further in view of Canton (US 6,145,393).

Meron et al. disclose a system, as described above, that fails to explicitly teach a system wherein the imaging device has a weight that is evenly distributed along a horizontal and a vertical axis of the imaging device; wherein the system includes at least one ballast weight; wherein the imaging device has a specific gravity that does not substantially exceed the specific gravity of the liquid; wherein the liquid has a diffraction coefficient substantially similar to that a diffraction coefficient of the housing.

However, **Canton** discloses a sensing device comprising an optical platform including:

(a) a housing 16 (see fig. 10) comprising:

(b) at least one friction reducing mechanism 18 disposed between the housing 16 and a sensing device 17 (see fig. 10);

wherein the friction-reducing mechanism 18 includes a liquid;

wherein the liquid 18 has a diffraction coefficient substantially similar to a diffraction coefficient of the housing 16;

wherein the liquid 18 is at least partially transparent;

wherein the liquid is oil (see; at least one friction reducing mechanism 18;

wherein the friction-reducing mechanism 18 includes a liquid;

wherein the liquid 18 has a diffraction coefficient substantially similar to a diffraction coefficient of the housing 16;

(c) a sensing device 17 (see fig. 10);

wherein the sensing device 17 has a weight that is evenly distributed along a horizontal and a vertical axis of the sensing device 17 (see col. 4, lines 16-20);

wherein the sensing device 17 has a specific gravity that does not substantially exceed the specific gravity of the liquid 18 (see col. 4, lines 6-8);

wherein the imaging device 20 includes a ballast weight (see col. 4, lines 20-31).

In regards to **claims 11-12 & 26**, Since Canton teaches a sensing device having a weight that is evenly distributed along a horizontal and vertical axis of the sensing device (see col. 4, lines 16-20 & 29-32), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Meron et al. as modified by Dunne et al. with a weight that is evenly distributed along a horizontal and vertical axis as taught by Canton in order to position the imaging device at the physical center of the system so as to achieve an imaging device that will not occur if acceleration forces are applied to the system.

In regards to **claim 28**, since Canton teaches a sensing device wherein the liquid has similar optical properties as the viewing port 19 of the housing 16 so that the liquid must also be transparent (i.e. similar diffraction coefficient of the housing) to the wavelengths of light required by the imaging system (see col. 4, lines 56-65), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was

made to provide the system of Meron et al. as modified by Dunne et al. with a liquid having a diffraction coefficient that is substantially to a diffraction coefficient of the housing as taught by Canton in order to allow the liquid and the housing to be transparent to the wavelengths of light required by the imaging system.

7. **Claims 5, 18 & 38-39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Meron et al. ('774) in view of Dunne et al. ('834) and further in view of Kovacs et al. (US 5,833,603).

Meron et al. as modified by Dunne et al. disclose a system, as described above, that fails to explicitly teach a housing that includes a semi-permeable membrane, at least one additional sensor selected from a temperature sensor and a pressure sensor.

However, **Kovacs et al.** teach that it is known to provide an in-vivo sensing system 44 with a semi-permeable membrane 126 (see figs. 10-11; col. 15, lines 25-49); wherein the sensor includes at least one additional sensor (see col. 8, lines 47-65). selected from an image sensor 98 (see col. 13, lines 5-12), a temperature sensor (see col. 10, lines 3-17) and a pressure sensor 108 (see col. 14, lines 59-62).

In regards to **claim 5**, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Meron et al. as modified by Dunne et al. with a semi-permeable membrane as taught by Kovacs et al. in order to detect the presence or absence of dissolved or free gases or ions.

In regards to **claims 18 & 38-39**, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Meron et al. as modified by Dunne et al. with a temperature sensor, a pressure or a pH sensor

as taught by Kovacs et al. in order to the measure the temperature, pressure or pH within the body lumen.

8. **Claim 46** is rejected under 35 U.S.C. 103(a) as being unpatentable over Meron et al. ('774) in view of Dunne et al. ('834) and further in view of Mullick et al. (US 2003/0167000).

Meron et al. as modified by Dunne et al. disclose a method, as described above, that fails to explicitly teach a step of repositioning a patient.

However, **Mullick et al.** teach a method for sensing an in-vivo site (see par 0018) comprising the steps of:

(a) providing an in-vivo sensing system comprising:

(i) a housing 42 (see figs. 2 & 3A-B; par 0055-0056);

wherein the housing 42 has a capsule shape (see figs. 2 & 3A-B);

wherein the housing is at least partially transparent (i.e. "transparent window 62") (see fig. 2);

(ii) a sensing device 48 (see par 0059);

wherein the sensing device includes an imaging device (see par 0059);

(iii) a transmitter 50 (see par 0062);

b) enabling an in-vivo sensing system 40 disposed within a housing 42 to be moved within the anatomy of a patient (see par 0055); wherein the in-vivo sensing system 40 includes an imaging device 48 (see par 0059);

(c) applying an external force (i.e. "gravitational force") to the in-vivo sensing system 40; wherein applying an external force includes repositioning the patient;

The Examiner notes that Mullick et al. teach an in-vivo system that performs diagnostic operations within the stomach of a patient while the patient performs activities of daily living (see par 0015) for a maximum of 72 hours (see par 0020); as such, both the patient and the in-vivo system are inherently subject to the gravitational force while the patient repositions while conducting the activities of daily living.

Both Meron et al. and Mullick et al. teach imaging devices that are swallowable (see respective abstracts); since Mullick et al. teach that an imaging device that allows a patient to use the device while still performing activities of daily living (see par 0015), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Meron et al. as modified by Dunne et al. with a step of repositioning the patient as taught by Mullick et al. in order to allow the patient to use the device while still performing activities of daily living.

9. **Claim 15** is rejected under 35 U.S.C. 103(a) as being unpatentable over Meron et al. ('774) in view of Dunne et al. ('834) and further in view of Gross (US 5,318,557).

Meron et al. as modified by Dunne et al. disclose an in-vivo system, as described above, that fails to explicitly teach a magnetic switch.

However, **Gross** discloses an in-vivo sensing system (see fig. 4) with a magnetic switch (i.e. reed switch) configured for controlling at least one electrical component of the sensing device (see col. 4, lines 54-58).

Dunne et al. teach a system for applying an external magnetic force (i.e. torque) to change the direction of an imaging device 24 (see fig. 12; col. 10, lines 54-65); since Gross teaches that it is known to provide an in-vivo sensing system with an electrical

switch, which can be magnetically actuated by a magnetic field externally of the subject (see col. 4, lines 54-58), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Meron et al. as modified by Dunne et al. with a magnetic switch as taught by Gross in order to selectively apply an external magnetic force to the change the direction of the imaging device by magnetically actuating the magnetic switch by a magnetic field external of the subject.

Response to Arguments

10. Applicant's arguments January 21, 2010 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 2003/0130562 to Barbato et al. discloses an imaging device and related method.

US 5,547,455 to McKenna et al. discloses an electronically steerable endoscope.

US 2005/0119577 to Taniguchi discloses an intracoelomic mobile body and capsule-type ultrasonic endoscope.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on Mon-Thurs, 8:00AM-6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rene Towa/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736